PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Hanry Yu et al..

Application No. 09/975,273

Filed: October 12, 2001

For: MULTI-LAYER CELL ENCAPSULATION FOR TISSUE ENGINEERING APPLICATIONS

Group Art Unit: 1651

Examiner: TO BE ASSIGNED

Atty Docket: 004814.00003

SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

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Sir:

Pursuant to the duty of disclosure under 37 CFR §§ 1.56 and 1.97-1.98, the documents listed on the attached Forms PTO-1449 are being brought to the attention of the Examiner in charge of the above-identified application to ensure formal consideration on the record. A copy of the documents is enclosed.

The Examiner is respectfully requested to initial the space adjacent each document entry on the Forms PTO-1449, and to return a copy of the initialed Forms PTO-1449 to confirm that the documents have been considered and have been officially made of record in this application.

If the Examiner has any questions or wishes to discuss this application, the Examiner is invited to telephone the undersigned representative at the number set forth below.

It is believed that no fee is due for this submission. However, should any fees be required for consideration of this paper, the Assistant Commissioner is authorized to charge our Deposit Account No. 19-0733.

Respectfully submitted,

BANNER & WITCOFF, LTD.

Date: June 16, '03

By: Paul M. Rivard

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Sheet 1 of 4

Complete If Known	
Application Number	09/975,273
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First Named Inventor	Hanry Yu et al.
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Attorney Docket Number	004814.00003

U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No.[1]	Document Number Number - Kind Code[2] (*if known*)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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	1	British Journal of Dermatology, Morphological and biochemical analyses on fibroblasts and self-produced collagens in a novel three-dimensional culture, 1997: 136: pp. 6-11.	
	2	The International Journal of Artificial Organs, Morphological and functional evaluation of isolated rat hepatocytes in three dimensional culture systems, Vol. 22. no. 11, 1999, pp. 778-785.	
	3	The International Journal of Artificial Organs, Evaluation of new small barium alginate microcapsules, Vol. 18, no. 2, 1995, pp. 96-102.	
	4	International Union Against Cancer Journal, Three-Dimensional Co-Culture of Human Monocytes and Macrophages with Tumor Cells: Analysis of Macrophage Differentiation and Activation, 66, pp. 645-652, 1996.	
	5	Transplantation Proceedings, Mixed Lymphocyte Islet Culture for Assessment of Immunoprotection by Islet Microencapsulation, Vol. 27, No. 6, December, 1995, pp. 3362-3363.	
	6	International Journal of Experimental Pathology, Multicellular spheroids: a three-dimensional in vitro culture system to study tumour biology, 1998, 79, pp. 1-23.	
	7	Elsevier Science Inc., Cell Transplantation, Highly Porous Polymer Matrices as a Three-Dimensional Culture System for Hepatocytes, Vol. 6, No. 5, pp. 463-468, 1997.	
	8	Elsevier Science Inc., Cell Transplantation, CTLA4-1g Prolongs Survival of Microencapsulated Neonatal Porcine Islet Xenografts in Diabetic NOD Mice, Vol. 6, No. 5, pp. 505-508, 1997.	
	9	Transplantation Proceedings, Efficacy of Microencapsulation of a Pancreatic B-Cell Line (MIN6) in an Agarose/PPSa Microbead as a Bioartificial Pancreas, Vol. 28, NO. 2, April 1996, pp. 1094-1096.	
	10	The International Journal of Artificial Organs, A Method for obtaining monodispersed cells from isolated porcine islets of Langerhans, Vol. 18, No. 1, 1995, pp. 34-38.	
	11	Cell Transplantation, The Effects of Microencapsulation on Pancreatic Islet Osmotically Induced Volumetric Response, Vol. 8, pp. 699-708, 1999.	
	12	Transplantation Proceedings, Microencapsulation Improves Canine Islet Survival In Vivo, Vol. 27, No. 6, December, 1995, pp. 3349-3350.	

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	13	J. Microencapsulation, Microencapsulation in yeast cells, Vol. 15, No. 6, 1998, pp. 761-773.	
	14	Bioplysical Journal, Characterization of Three-Dimensional Tissue Cultures Using Electrical Impedance Spectroscopy, Vol. 76, May 1999, pp. 2640-2648.	
	15	Elsevier Science, Inc., Cell Transplantation, Evaluation of a Purified Enzyme Blend for the Recovery and Function of Canine Pancreatic Islets, Vol. 7, No. 4, pp. 365-372, 1998.	
	16	Cell Transplantation, The Rescue Effect of 15-Deoxyspergualin on Intraperitoneal Microencapsulated Xenoislets, Vol. 8, pp. 307-315, 1999.	
	17	The International Journal of Artificial Organs, Effect of donor strains and age of the recipient in the use of microencapsulated hepatocytes to control hyperbilirubinemia in the Gunn rat, Vol. 18, No. 5, 1995, pp. 332-339.	
	18	Artificial Organs, High Cell-Density Culture System of hepatocytes Entrapped in a Three-Dimensional Hollow Fiber Module with Collagen Gel, Vol. 19, No. 2, pp. 191-193, 1995.	
	19	Artificial Organs, Evaluation of Modified Alginate-Chitosan-Polyethlene Glycol Microcapsules for Cell Encapsulation, Vol. 23, No. 10, pp. 894-903, 1999.	
	20	Springer-Verlag, Appl Microbiol Biotechnol, Biocompatible alginate from freshly collected *Laminaria pallida* for implantation, Vol. 53, pp. 224-229, 2000.	
	21	Springer-Verlag, J Mol Med, Cell Therapy using microencapsulated 293 cells transfected with a gene construct expressing CYP2B1, an ifosfamide converting enzyme, instilled intra-arterially in patients with advanced-stage pancreatic carcinoma: a phase I/II study, Vol. 77, pp. 393-398, 1999.	
	22	John Wiley & Sons, Inc., Studies on small (<350μm) alginate-poly-L-lysine microcapsules. III. Biocompatibility of smaller versus standard microcapsules, pp. 116-120, 1999.	
	23	Diabetes, Why Do Microencapsulated Islet Grafts Fail in the Absence of Fibrotic Overgrowth?, Vol. 48, pp. 1381-1388, July 1999.	
	24	Cancer Research, E7-transduced Human Breast Epithelial Cells Show Partial Differentiation in Three-dimensional Culture, Vol 59, pp. 6042-6045, December 15, 1999.	
	25	J. Microencapsulation, Calcium alginate microparticles for oral administration: I effect of sodium alginate type drug release and drug entrapment efficiency, Vol. 16, No. 3, pp. 275-290, 1999.	
	26	J. Microencapsulation, Calcium alginate microparticles for oral administration: II effect of formaulation factors on drug release and drug entrapment efficiency, Vol. 16, No. 3, pp. 291-301, 1999.	
	27	John Wiley & Sons, Inc., A Sensitivity Study of the Key Parameters in the Interfacial Photopolymerization of Poly(ethyleneglycol) Diacrylate upon Porcine Islets, pp. 655-665, 1998.	

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	28	Springer-Verlag, World J Urol, Controlled release of therapeutic agents: slow delivery and cell encapsulation, Vol. 18, pp. 80-83, 2000.	
	29	Elsevier Science Inc., TI in vivo delivery of heterologous proteins by microencapsulated recombinant cells, Vol. 17, pp. 78-83, February 1999.	
	30	Elsevier Science Inc., Transplantation Proceedings, Fructose Protects Rat Hepatocytes Against Hypoxic Injury During the Process of Isolation and Microencapsulation, Vol. 31, pp. 1080-1083, 1999.	
	31	Springer-Verlag, J Mol Med, Transplantation of islets using microencapsulation: studies in diabetic rodents and dogs, Vo. 77, pp. 206-210, 1999.	
	32	Springer-Verlag, J Mol Med, Factors influencing the properties and performance of microcapsules for immunoprotection of pancreatic islets, Vol. 77, pp. 199-205, 1999.	
	33	Springer-Verlag, J Mol Med, Synergistic effect of microencapsulation and immunoalteration on islet allograft survival in bioartificial pancreas, Vol. 77, pp. 193-198, 1999.	
	34	John Wiley & Sons, Inc., Encapsulation of various recombinant mammalian cell types in different alginate microcapsules, pp. 587-596, 1998.	
	35	Experimental Cell Research, Induction of Apoptotic Cell Death in Vascular Endothelial Cells Cultured in Three-Dimensional Collagen Lattice, Vol. 248, pp. 498-508, 1999.	
	36	Journal of Cellular Phsiology, Long-Term Expression of Differentiated Functions in Hepathocytes Cultured in Three-Dimensional Collagen Matrix, Vol. 177, pp. 553-562, 1998.	
	37	Journal of Surgical Research, Optimization of the Microencapsulated Islet for Transplantation, Vol. 76, pp. 7-10, 1998.	
	38	Elsevier Science Ltd., HEMA/MMMA microcapsule implants in hemiparkinsonian rat brain: biocompatibility assessment using {^{3}H}PK11195 as a marker for gliosis, Biomaterials, Vol. 19, pp. 829-837, 1998.	
	39	Elsevier Science Inc., Transplantation Proceedings, Microencapsulation Improves Viability of Islets Form CSK Miniature Swine, Vol. 30, p. 491, 1998.	
	40	John Wiley & Sons, Inc., Entrapment of islets into reversible disulfide hydrogels, pp. 115-123, 1998.	
	41	Elsevier Science Ltd., Drug delivery to the nervous system, Vol., 15, pp. 410-418, October 1997.	
	42	Elsevier Science Inc., Transplantation Proceedings, Microencapsulation of Neonatal Porcine Islets: Long-Term Reversal of Diabetes in Nude Mice and In Vitro Protection From Human Complement Mediated Cytolysis, Vol. 29, p. 2128, 1997.	

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